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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,658	01/24/2005	Hideki Murata	09859/0202424-US0	8728
7278	7590	08/09/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			FERNANDEZ, SUSAN EMILY	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 08/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/522,658

Applicant(s)

MURATA ET AL.

Examiner

Susan E. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/20/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The preliminary amendment filed January 24, 2005, has been received and entered.

Claims 1-6 are pending.

Claim Objections

Claim 3 is objected to because of the following informalities: Claim 3 recites "from-basidiomycetes." The hyphen should be deleted such that the recitation reads "from basidiomycetes." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are rendered indefinite by the recitation "a temperature of 0°C or above and 30°C or below." A temperature "of 0°C or above" encompasses temperatures above 30°C, while a temperature of "30°C or below" encompasses temperatures below 0°C, therefore, it is unclear how a temperature can be both. Similarly, the recitation "a temperature of more than 30°C and 80°C or below" in claim 1 is confusing for the same reason. For examination purposes, the recitation "a temperature of 0°C or above and 30°C or below" will be read as a temperature selected from the range of 0°C to 30°C, and the recitation "a temperature of more

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than 30°C and 80°C or below” will be read as a temperature selected from the range of 30°C and 80°C. Because of claims 1 and 2, claims 1-6 are rejected under 35 U.S.C. 112, second paragraph.

Claim 1 is rendered indefinite by the recitation “the solution” at step [2], since the recitation lacks antecedent basis. It is suggested that “the solution” be replaced with “the resulting mixture.” Similarly, the recitation “the solution” at step [4] lacks antecedent basis, and it is suggested that “the solution” at step [4] be replaced with “the resulting mixture.” Finally, it is unclear how the last step recited (step [4]) relates to the production of ubiquinone-10-containing solution, nor is it clear that a ubiquinone-10-containing solution is obtained. For examination purposes, the mixture obtained after step [4] is performed is considered a ubiquinone-10-containing solution. Because of claim 1, claims 1-6 are rejected under 35 U.S.C. 112, second paragraph.

Claim 2 is confusing because of the phrasing used in the claim. First, at lines 1 and 2, the claim recites “adding a methanol solution **again** to the insoluble matter” (emphasis added), but parent claim 1 never recites adding a methanol solution to the insoluble matter. It is suggested that “again” in the above recitation be deleted. Moreover, the recitation “the insoluble matter obtained in step [2]” is confusing, since it appears that claim 2 requires the repetition of the claim 2 steps once or more times. Therefore, the insoluble matter that is being treated with methanol solution would not be the insoluble matter of step [2] after one iteration of the steps recited in claim 2. For examination purposes, claim 2 will be read as follows: The process according to claim 1, wherein, following step [2] and before the subsequent step [3], the steps of adding a methanol solution to recovered insoluble matter to a final concentration of 50 to 100 v/v%,

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retaining a resulting mixture at a temperature of 0°C or above and 30°C or below, and subsequently separating and recovering insoluble matter, are repeated one or more times.

Claim 5 is confusing since the claim alleges to be drawn to “a process for producing a crystal of ubiquinone-10,” but does not clearly give steps to describe how the crystal is produced. Instead, it only discusses the deposit of a produced crystal of ubiquinone-10. Additionally, claim 5 is indefinite since “depositing the crystal of ubiquinone-10” does not clearly define a step. It is not clear where the crystal is being deposited. Thus, claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 56-131394.

JP '394 discloses a method wherein 10 g of crude coenzyme Q₁₀ (which is another term for ubiquinone-10, see abstract of Frei et al, PNAS, 1990, 87: 4879-4883) produced by fermentation of *Protaminobacter ruber* (a bacteria), was dissolved in a solution which was furthered treated with 20 ml of a 28% NH₄OH-MeOH (ammonium hydroxide-methanol) (5:95) mixture at 10°C for 20 minutes. See the CAPLUS English abstract. The crude coenzyme Q₁₀ can be considered to be a processed product of a culture of ubiquinone-10-producing microorganism, or a partially purified product of ubiquinone-10. This step meets nearly all the requirements of step [1] of instant claim 1, except that it does not teach the volume of the methanol solution relative to the volume of product being treated as recited in instant claim 1. Next, after retaining the resulting mixture at 10°C for 20 minutes, the NH₄OH-MeOH layer is discarded, and this step meets the limitations of step [2] of instant claim 1. Then, the remaining impurities (insoluble matter) are extracted a second time with 20 mL of 95% MeOH solution at 10°C for 20 minutes. This step meets nearly all the limitations of step [3] of instant claim 1, except for the temperature at which the resulting mixture is retained. Next, a purified coenzyme Q₁₀ is recovered from this extraction, thus insoluble matter had to have been removed, thus step [4] of instant claim 1 is taught by the reference. Finally, the purified coenzyme Q₁₀ is crystallized from acetone.

As discussed above, the methods disclosed in JP '394 differ from the instant invention in that JP '394 does not teach the final concentration of 50 to 100 v/v% of methanol solution in the total volume of the resulting mixture, as recited in step [1] of instant claim 1. Nevertheless, the selection of a specific volumetric ratio of methanol solution to the total resulting mixture would

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have been a routine matter of optimization on the part of the artisan of ordinary skill in the art, said artisan recognizing that the extraction of impurities would have been dependent on the concentration of the methanol solution present in preparing the resulting mixture. Thus, limitations recited in step [1] of instant claim 1 are rendered obvious by the reference.

Additionally, as discussed above, the methods disclosed in JP '394 differ from the instant invention in that JP '394 does not teach the temperature at which the resulting mixture is retained after the insoluble matter is treated with methanol solution, as recited in step [3] of instant claim 1. Nevertheless, the selection of specific suitable temperatures for retaining the resulting mixture, including that claimed, clearly would have been an obvious matter of optimization on the part of the artisan of ordinary skill in the art. Thus, all limitations of step [3] of instant claim 1 are rendered obvious by the reference.

Therefore, JP '394 renders obvious instant claims 1 and 3. Given that a crystallized pure coenzyme Q₁₀ is taught by JP '394 as the final product of their method, instant claim 5 is also rendered obvious.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have repeatedly treated the insoluble matter with the 95% methanol solution following initial treatment of crude coenzyme Q₁₀ with a methanol solution, therefore rendering claim 2 obvious. One of ordinary skill in the art would have been motivated to repeat this step in order to have further purified the insoluble matter by extracting more of the impurities by performing extra extractions. Repetition of methanol treatment would have ensured maximal extraction and maximal removal of impurities. The repetition of process steps

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would have been prima facie obvious in the absence of new or unexpected results. Thus, claim 2 is rendered obvious by the reference.

Finally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used any of the forms recited in claim 4 as the crude coenzyme Q₁₀ required for the practice of JP '394. One of ordinary skill in the art would have been motivated to do this since there would have been a reasonable expectation of success in successfully purifying coenzyme Q₁₀ with any of these forms. Moreover, one would have been motivated to have used these forms since these forms may be stored for long periods of time. Thus, claim 4 is rendered obvious by the reference.

A holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

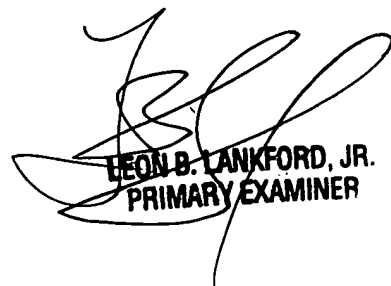
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651

sef



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PRIMARY EXAMINER